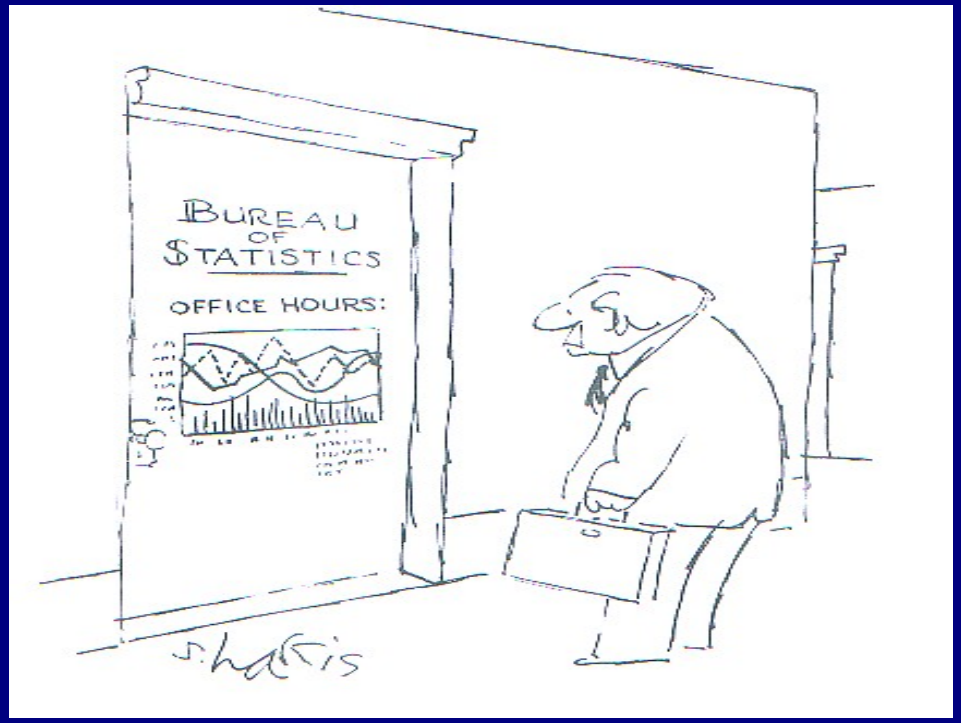
Privacy Rules & Research



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MEDICAL DATA PRIVACY

Health Insurance Portability Act of 1996
Standards for Privacy of Individually Identifiable Health Information

- **Confidentiality: A tool for the protection of privacy. It mandates controls on personal data, limiting access and disclosure.**

- **Privacy: The specific right of an individual to control the collection, use, and disclosure of personal information.**

HIPAA
Standards for Privacy of Individual Identifiable Health Information

- Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996
- "Privacy of Individually Identifiable Health Information"
  - 45 CFR Part 160-General Administrative Requirements
  - 45 CFR Part 164-Security and Privacy

HIPAA Legislation

Purpose:

- Improve portability & continuity of health insurance coverage

- Improve access to long term care services and coverage

- ***Simplify*** **the administration of health care – source of Privacy Rule**

Secretary HHS provided recommendations and privacy regulations as the Congress failed to pass privacy legislation by August 21, 1998

HIPAA: THE PRIVACY RULE

Legislation

HIPAA under PL 104-191 requires compliance with several standards, including

- **Standards for Electronic Transactions and Code Sets**
- Privacy
- **Security Standards**
- Electronic Signature Standards
- National Standard Employer Identifier
- National Standard Health Care Provider Identifier
- National Standard Health Plan Identifier

HIPAA: THE PRIVACY RULE
The Basics

Final Rule Published: Dec 2000
Rule Published: August 2002
Compliance Date: April 14, 2003

- Consumer control = Rights for individual patient
- Boundaries on use and release
- Ensuring security
- Accountability and penalties
- Balancing public responsibility with protections
- Preserving strong state laws

HIPAA: THE PRIVACY RULE
The Basics

The HIPAA privacy rule states that a covered entity may not use or disclose protected health information (PHI) unless the patient agrees to the use or disclosure, or the use or disclosure is specifically required or permitted by the HIPAA regulations.

"Use" applies to internal utilization or sharing of Individually Identifiable Health Information (IIHI)

HIPAA: THE PRIVACY RULE
The Definitions

- **Disclosure**
  - **The release, transfer, provision of access to, or divulging in any other manner of information *outside* the entity holding the information.**

HIPAA: THE PRIVACY RULE
The Covered Entities

Covered entities transmit health information in (standard) electronic transactions

- Health care providers
- Health Plans
- Health care clearinghouses

✿ Other Entities

- Business Associates

HIPAA: THE PRIVACY RULE
The Definitions

- **Health Care Provider**
  - **A provider of services as defined in 42 of the U.S.C., a provider of medical or health services as defined in 42 U.S.C., and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.**

HIPAA: THE PRIVACY RULE
The Definitions

- **Health care operations**
  - Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities.

HIPAA: THE PRIVACY RULE
The Definitions

- **Business Associate: A covered entity participating in an organized health care arrangement that performs a function or activity involving the use or disclosure of individually identifiable health information, including…. utilization review, quality assurance….**

HIPAA: THE PRIVACY RULE
The Definitions: IIHI

- ***Individually identifiable health information*: Information that is a subset of health information, including demographic information collected from an individual, and:**
  - Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; and
    - Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and
    - That identifies the individual; or
    - With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

HIPAA: THE PRIVACY RULE
The Definitions: PHI

- **Protected health information (PHI):** ***Individually identifiable health information*** **that is:**
  - **Transmitted by electronic media;**
  - **Maintained in any medium described in the definition of *electronic media*; or**
  - **Transmitted or maintained in any other form or medium.**

HIPAA: THE PRIVACY RULE
The Covered Information

- Protected health information (PHI) is:
  - Individually identifiable health information including demographics
  - Held by covered entities or their business associates
  - PHI is not limited to the contents of a patient's medical record it includes:
    - all electronic, paper and verbal individually identifiable health information.
  - De-identified information is not PHI.
  - Tissue is not PHI-the information connected to it maybe

HIPAA: THE PRIVACY RULE
DE-IDENTIFICATION of PHI

- **Can be used without authorization (still requires IRB review)**

- **<u>Standard:</u> De-identification of protected health information. Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information.**

- **Proof**
  - A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable: Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information by an anticipated recipient to identify an individual who is a subject of the information; and documents the methods and results of the analysis that justify such determination

De-Identification Requirements
"Safe Haven"

- Names;
- All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, zip code (20,000 people rule)
- All elements of dates (except year) directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89
- Telephone numbers;
- Fax numbers;
- Electronic mail addresses;
- Social security numbers;
- Medical record numbers;
- Health plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers, serial #, license plate numbers;
- Device identifiers & serial #
- Web Universal Resource Locators
- Internet Protocol (IP) address
- Biometric identifiers,(finger voice)
- Full face photographic images & any comparable images; and
- Any other unique identifying number, characteristic, or code*

HIPAA: The PRIVACY Rule
Permitted Uses & Disclosures

MHS may use or disclose PHI for treatment, payment and health care operations. Permitted uses and disclosures include:

- as required by law
- avert serious threats to health or safety
- specialized government functions
- judicial and administrative proceedings
- law enforcement purposes
- medical facility patient directories
- cadaver organ, eye or tissue donation purposes
- victims of abuse, neglect or domestic violence
- inmates in correctional institutions
- workers' compensation
- **research purposes**
- public health activities
- health oversight activities
- about decedents

HIPAA: THE PRIVACY RULE
The Definitions

Permitted and Required Uses and Disclosures of PHI that May Be Made Without Consent, Authorization or Opportunity to Object

- **RESEARCH--Availability of PHI by waiver by IRB or Privacy Board: in limited cases to researchers when their research has been determined to not adversely affect privacy rights, such as research in which personally identifying information will not be disclosed by the researcher. (DHHS)**

Privacy Rule & Research

- **Why?**
  - **Creates equal standard for research not currently covered by Federal Protections**
  - ***Different in various aspects from "Common Rule" and FDA Subject Protection Regulations***
  - **While conducting research, the researcher may be required to create, obtain, use, and/or disclose IIHI.**
- **What's covered?**
  - **Anytime protected health information is required.**
    - **Basic science**
    - **Social science studies**
    - **Behavioral science studies**
    - **Chart review**
    - **Epidemiology**
    - **Clinical trials**

Permitted Uses and Disclosures for Research

- Research Use/Disclosure with Authorization

- Research Use/Disclosure without Authorization
  - Documented IRB/Privacy Board Approval of a Waiver of Authorization
  - Preparatory to Research
  - Protected Health Information of Decedents
  - Use of Limited Data Sets with a Data Use Agreement

Review and Approval Procedures IRB/Privacy Board

- An IRB must follow the requirements of the **Common Rule**

- A IRB/Privacy Board must review the proposed research at convened meetings at which a majority of the privacy board members are present, including at least one “non affiliated” member, and the waiver must be approved by the majority of the members present at the meeting

- A IRB/Privacy Board may use an expedited review procedure if the research involves no more than minimal risk to the privacy of the individuals who are the subject of the PHI for which use or disclosure is being sought

AUTHORIZATION

- **An *Authorization* is a customized document that gives covered entities permission to use specified PHI for specified purposes, which are generally other than TPO, or to disclose PHI to a third party specified by the individual. It covers only the uses and disclosures and only the PHI stipulated in the authorization; it has an expiration date; and, in some cases, it also states the purpose for which the information may be used or disclosed (research).**
- **This is different from *Informed Consent* and the documentation required by the Common Rule or FDA standards.**
- **Both can be combined in a single research subject agreement document.**

AUTHORIZATION REQUIREMENTS

- The authorization must be in plain language **(8th grade level)** Required components:
- A description of the information to be used/disclosed identifying the information in a specific & meaningful fashion
- The name of the person(s) authorized to make the requested use or disclosure
- The name of the person(s)/agencies to whom the requested disclosure may be made. *Important for Adverse Event reporting.*
- An expiration date (including indefinite) or expiration event
- Description of the individual's right to revoke the authorization in writing, the exceptions to the right to revoke, together with a description of how the individual may revoke the authorization

AUTHORIZATION REQUIRMENTS

- A statement that information used or disclosed pursuant to the authorization may be subject to redisclosure by the recipient (another entity) and be no longer protected by the Rule
- Signature of the individual and date
- If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual
- A description of the extent to which such PHI will be used or disclosed to carry out treatment, payment, or health care operations

AUTHORIZATION REQUIREMENTS

If an authorization is requested by a Principal Investigator for use or disclosure of PHI that the PI maintains (as opposed to the PHI created by the research) the authorization must also contain:

- ✓ **A description of each purpose of the requested use or disclosure.**
- ✓ **A statement that the individual may inspect or copy the PHI to be used or disclosed, and may refuse to sign the authorizations.**
- ✓ **If use or disclosure of the requested information will result indirect or indirect remuneration to the PI from a third party, a statement that such remuneration will result.**
- ✓ **A statement that subject's access rights may be suspended while a clinical trial is in progress and that right to access will recommence at end clinical trail.**

Permitted Uses and Disclosures for Research

Research Use/Disclosure without Authorization

A covered entity may use or disclose protected health information (PHI) for research, regardless of the source of the funding of the research, pursuant to a waiver of authorization contingent on:

- IRB or Privacy Board approval of a waiver of authorization [45 CFR 164.512(i)2(ii)]
  - Three criteria
- Documentation of waiver approval
  - 5 components

Approval of a Waiver

Documented approval of a waiver must be obtained from either an

1. **Institutional Review Board (IRB), or**

2. **A Privacy Board**
   - **Members with varying backgrounds and appropriate professional competency**
   - **Includes at least one member who has no affiliation with the covered entity, the entity sponsoring the research nor the any one else affiliated with these entities**

Waiver Criteria

- The use or disclosure of PHI involves no more than minimal risk to the individuals
  - There is an adequate plan to protect the identifiers from improper use and disclosure
  - There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law
  - There are adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted.
  - The waiver will not adversely affect the privacy rights and the welfare of the individuals

Waiver Criteria

- The research could not practicably be conducted without the waiver
- The research could not practicably be conducted without access to and use of the PHI

- COMMON RULE: The privacy risks to individuals whose PHI is to be used or disclosed are reasonable in relation to the anticipated benefits if any to the individuals and the importance of the knowledge that may reasonably be expected to result from the research

Documentation of Waiver Approval Components

Documentation of a waiver approval must include

- A statement identifying the IRB or privacy board and the date on which the waiver was approved
- A statement that the IRB or privacy board has determined that the waiver satisfies the required criteria
- A brief description of the PHI for which use or access has been determined to be necessary by the IRB or privacy board
- A statement that the waiver has been reviewed and approved under either normal or expedited review procedures
- The signature of the chair or other member, as designated by the chair, or the IRB or the privacy board.

Investigator Responsibilities

- **Disclosure tracking**
  - Subjects have right to accounting of disclosures of PHI for six years prior to request or since 4/13/2003 compliance
    - Excluded are limited data sets & disclosures pursuant to subjects authorization
    - Simplified procedures for disclosures that involve at least 50 records.
- **Minimum Standard**
  - Use or disclosure of the *minimum* necessary PHI required for the research.

PREPARATORY TO RESEARCH

IRB/Privacy Board obtains from the researcher representations that:

- ✓ Use or disclosure is required solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory for research

- ✓ No PHI will be removed from the covered entity by the researcher in the course of the review

- ✓ The PHI for which use or access is sought is necessary for the research purposes

RESEARCH ON DECEDENT'S INFORMATION

PRIVACY RULE COVERS PHI OF DECEASED INDIVIDUALS

Differs from *Common Rule,* that does not protect decedents as research subjects.

To obtain approval from IRB/Privacy Board researcher provides:

- ✓ Representation that the use or disclosure is sought solely for research on the PHI of decedents
- ✓ Documentation, at the request of the covered entity, of the death of such individuals, and
- ✓ Representation that the PHI for which use or disclosure is sought is necessary for the research purposes

RESEARCH ON DECEDENT'S INFORMATION

Researcher Provides:

- ✓ Representation that the use or disclosure is sought solely for research on the PHI of decedents
- ✓ Documentation, at the request of the IRB/Privacy Board, of the death of such individuals
- ✓ Representation that the PHI for which use or disclosure is sought is necessary for the research purposes

LIMITED DATA SET

- **Allows use/disclosure without authorization**
- **Excludes specific identifiers**
  - **15 of 18 personal identifiers**
- **Includes**
  - **Geographic (town,city,state,zip code)**
  - **Dates (birth/death dates, age, admission & discharge)**
  - **Unique identifiers (number*, code*, characteristics other than in the 15 identifiers that are specifically disallowed)**

LIMITED DATA SET

- **Data Use Agreement**
  - **Establishes the permitted uses/disclosures of the LDS by the researcher consistent with the defined purposes of the research. May not include any use/disclosure that would violate the rule.**
  - **Limit who can use and receive the data.**
  - **Require agreement to following:**
    - **Not to use/disclose information other than permitted by agreement or otherwise required by law.**
    - **Use of appropriate safeguards to protect data.**
    - **Report to IRB/PB any use/disclosure not provided by agreement at time it occurs.**
    - **Ensure that any agent to whom researcher provides data agrees to same conditions for use/disclosure of LDS as primary agreement.**
    - **Not to identify the information or CONTACT THE INDIVIDUAL.**

RECRUITMENT OF SUBJECTS

- **Included under general authorization requirements**
  - **Classified as research**
  - **May disclose information from database for subject recruitment only after subject authorization or authorization waiver obtained**
    - **To approach subject identified under waiver, approach must be approved by IRB/Privacy Board**
  - **Use of Limited Data Sets**
    - **Conditions: Info. Cannot be used to contact subjects; prohibited identifiers cannot be collected from prospective subjects**

Individually Identifiable Health Information
Use of Code

- **Coded Information covered by *Common Rule***
  - **Indirectly Identifiable**
  - **Data only anonymized by permanent destruction of code or link**
- **Coded information not covered by Privacy Rule**
  - **Code covered by Privacy Rule**
    - **Directly Identifiable**
  - **Institution or Researcher holding code**

WEB RESOURCES FOR HIPAA& RESEARCH

- **NIH/HHS site for the booklet and other references for research is: http://www1.od.nih.gov/osp/ospp/hipaa/default.asp**

- **Updated site for Office of Civil Rights) is: http://www.hhs.gov/ocr/hipaa/privacy.html**

RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS:ETHICAL ISSUES AND POLICY GUIDANCE

VOLUME I & VOLUME II (COMMISSIONED PAPERS)

Report and Recommendations of the National Bioethics Advisory Commission Rockville, Maryland August 1999

ETHICAL AND POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS

VOLUME I & VOLUME II (COMMISSIONED PAPERS)

Report and Recommendations of the National Bioethics Advisory Commission Rockville, Maryland August 2001

NATIONAL BIOETHICS ADVISORY COMMISSION (NBAC
ETHICAL AND POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS
May 18, 2001

Recommendation 3.3: A unified, comprehensive federal policy embodied in a single set
of regulations and guidance should be created that would apply to all types of research
involving human participants (see Recommendation 3.2).

Recommendation 3.4: Federal policy should cover research involving human participants that entails systematic collection or analysis of data with the intent to
generate new knowledge. Research should be considered to involve human participants
when individuals 1) are exposed to manipulations, interventions, observations, or other
types of interactions with investigators or 2) are identifiable through research using

Human Tissue Repositories

- Human tissue repository:
  - **Any collection of specimens that are identifiable and either are or have the potential to be distributed to others may be considered a repository.**
  - **Collections containing specimens that are not identifiable (linked to donor) in anyway are also repositories but samples obtained from them may be eligible for exemption #4 in 45 CFR 46.101(b)**

Human Tissue Repositories

- **All identifiable tissue collected for research purposes (immediate and storage)should require IRB review at site of collection.**
  - **Written informed consent from donor**
    - **Information about repository**
    - **How tissue will be used/shared**

Human Tissue Repositories

- A tissue repository that distributes materials requires an IRB (OHRP approved assurance) that sets conditions under which tissue distributed.
  - Privacy
  - Conditions of original collection consent
  - Intended purpose of use based on information from researcher requesting tissue

Human Tissue Repositories

- **The IRB at the repository institution may either:**
  - **Require establishment of a committee to review each individual request for tissue to assure that IRB conditions for sharing are met and conform to purpose(s) stated in original collection consent.**
  - **Perform this function itself.**

Human Tissue Repositories

- **Researcher that is recipient of tissue sample must follow conditions specified by the repository IRB.**
  - **This may include review and approval by the IRB at the receiving institution.**

Tissue Banking
Sources

- Specimens obtained from routine clinical procedures and retained for future research activities.
- Specimens obtained for a specific research protocol and retained for future studies
- Specimens collected in the past for various reasons, not specifically for research purpose, and retained. (Retrospective specimen collections)

Categories of Human Biological Materials

Repository Collections

Unidentified specimens: For these specimens, identifiable personal information was not collected or, if collected, was not maintained and cannot be retrieved by the repository.

Unidentified samples: Sometimes termed "anonymous," these samples are supplied by repositories to investigators from a collection of unidentified human biological specimens.

Categories of Human Biological Materials Research Samples

Unlinked samples: Sometimes termed "anonymized," these samples lack identifiers or codes that can link a particular sample to an identified specimen or a particular human being.

Coded samples: Sometimes termed "linked" or "identifiable," these samples are supplied by repositories to investigators from identified specimens with a code rather than with personally identifying information, such as a name or Social Security number.

National Bioethics Advisory Commission (NBAC)

ategories of Human Biological Materials

Research Samples

Identified specimens: These specimens are linked to personal information in such a way that the person from whom the material was obtained could be identified by name, patient number, or clear pedigree location (i.e., his or her relationship to a family member whose identity is known).

Identified samples: These samples are supplied by repositories from identified specimens with a personal identifier (such as a name or patient number) that would allow the researcher to link the biological information derived from the research directly to the individual from whom the material was obtained.

National Bioethics Advisory Commission (NBAC)

- **Human Tissue Repositories** collect, store, and distribute human tissue materials for research purposes. Repository activities involve three components: (i) the **collectors** of tissue samples; (ii) the **repository** storage and data management center; and (iii) the **recipient** investigators.

- If supported by the Department of Health and Human Services (HHS), each component must satisfy certain **regulatory requirements.**

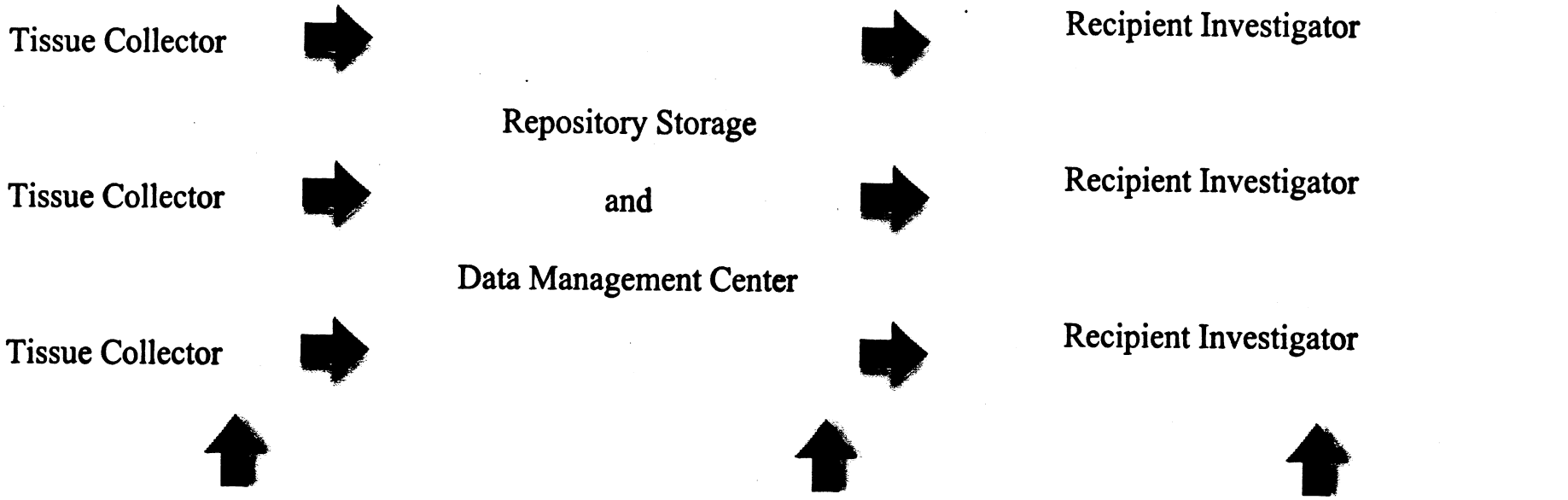


Chart 1: NBAC's Proposed Process for Research Using Human Biological Materials

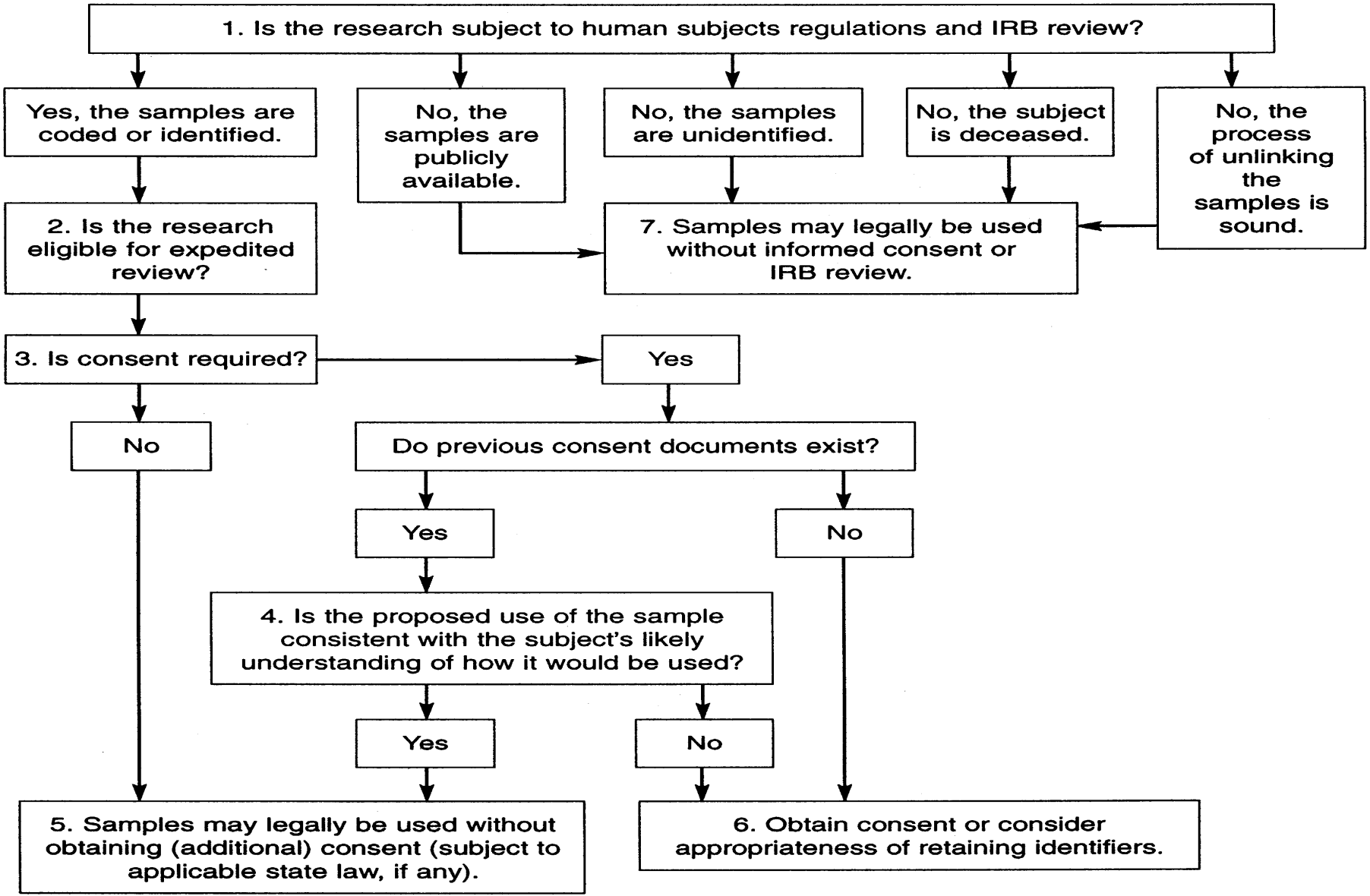


Chart 3: IRB Review for Research with Human Biological Materials

Guidelines for applying the exemption stated at 45 CFR 46.101(b)(4) and criteria for expedited review at §46.110.

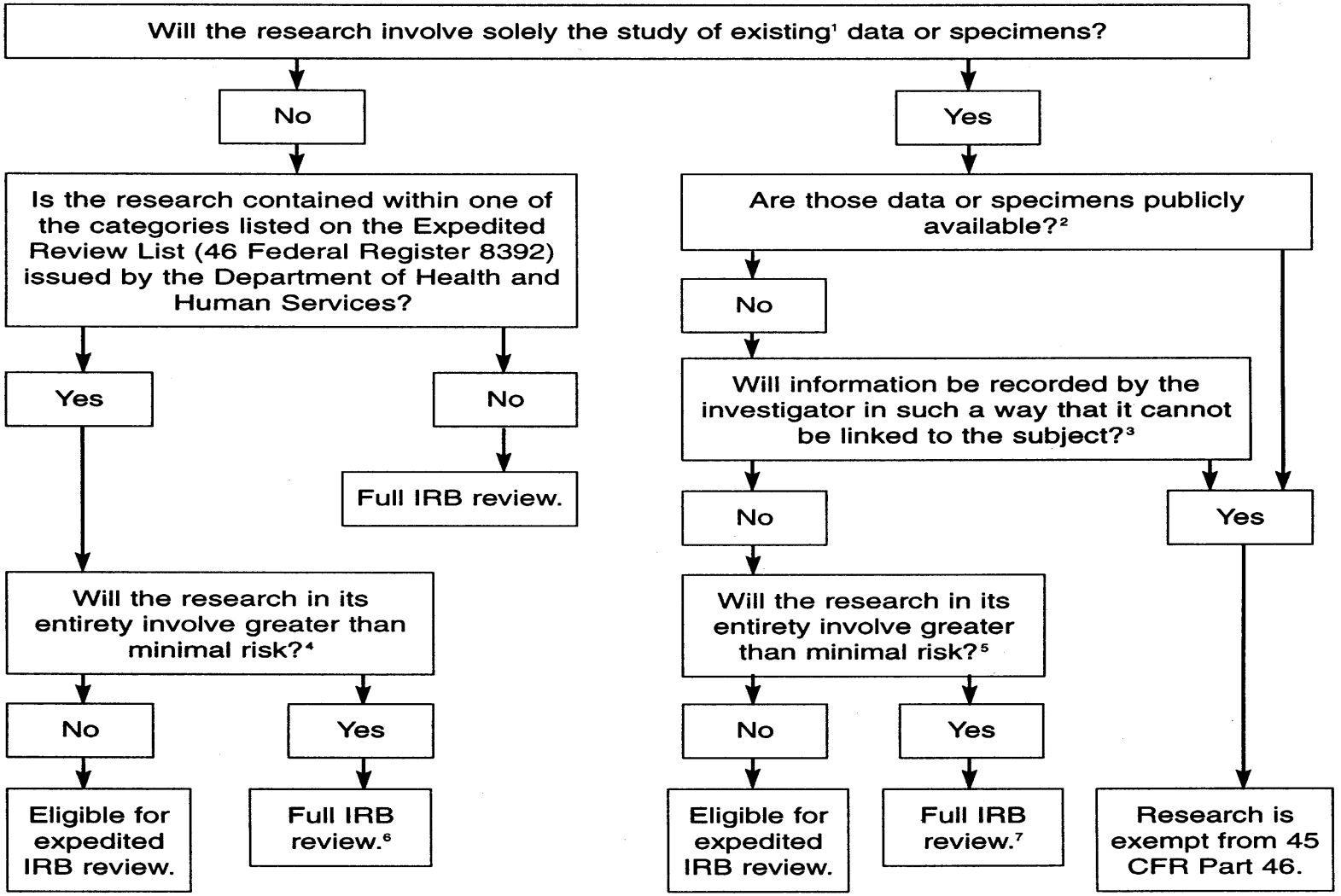
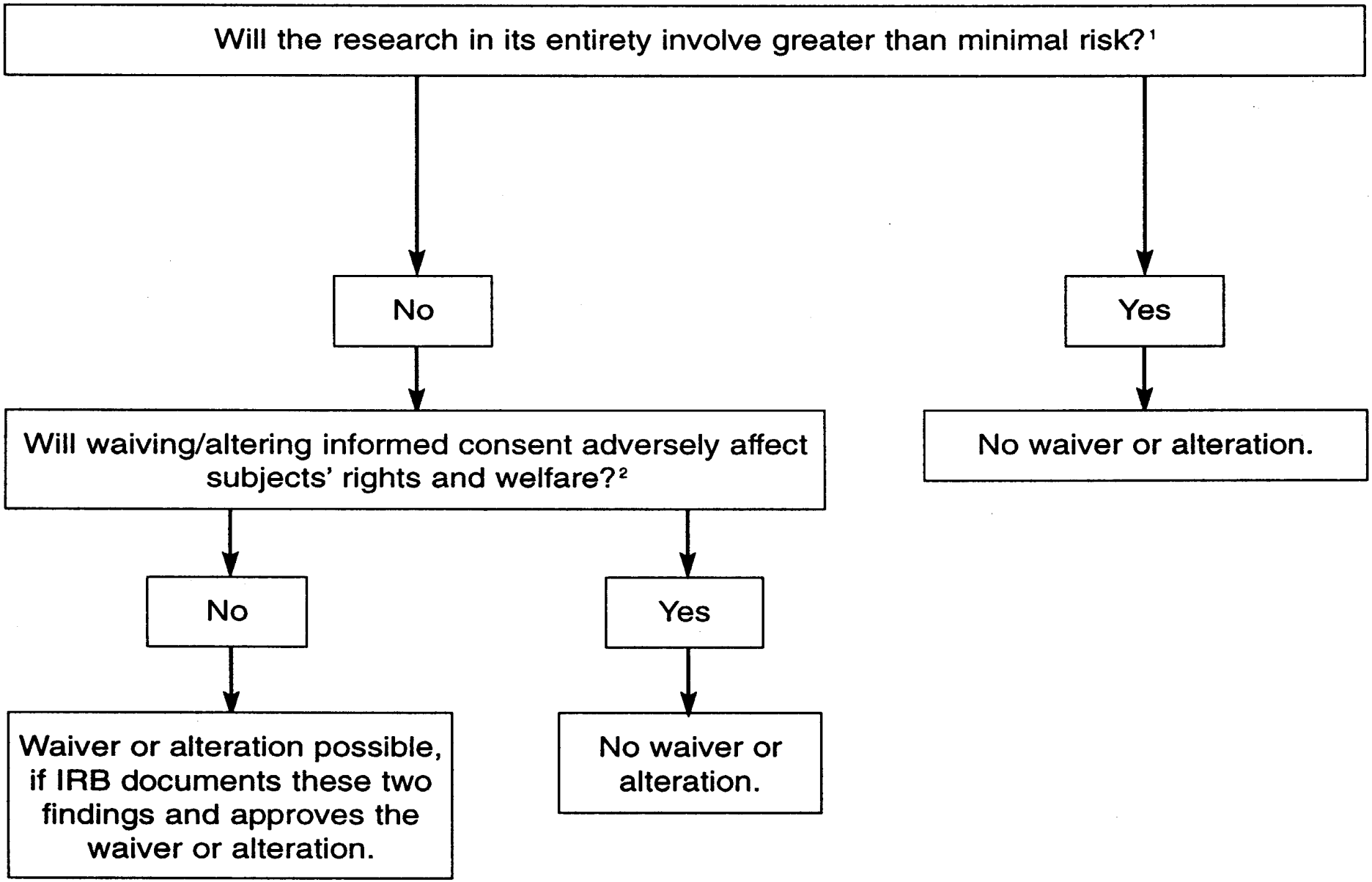


Chart 4: NBAC's Proposed Informed Consent Requirements for Research with Human Biological Materials[1]



Policy Sites and Documents

- **Information for Researchers Using Human Specimens**
  - **http://www-cdp.ims.nci.nih.gov/policy.html**
- **Report and Recommendations of the National Bioethics Advisory**
  - **http://www.georgetown.edu/research/nrcbl/nbac/pubs.html**
- **OHRP**
  - **http://ohrp.osophs.dhhs.gov/humansubjects/guidance/reposit.htm**